

(Discussion)

- 1. The primary endpoints for Studies 302 and 305 were changed from a patient-level concordance of binodenoson and adenosine myocardial perfusion images (MPIs) to a comparison of *average* summed difference scores (SDSs).**

Do the revised endpoints provide a robust measure of agreement between binodenoson and adenosine MPI?

(Discussion)

- 2. All three phase 3 studies failed to achieve success upon the “original” primary endpoint of MPI *concordance*. However, success was achieved upon the “revised” endpoint of comparisons of *average* SDSs.**

Does this inconsistency impact your assessment of the agreement between binodenoson and adenosine MPIs?

(Discussion)

- 3. Knowledge of MPI results may have impacted the decision to perform coronary arteriography in the phase 3 study population; ~ 16% of the population underwent the procedure.**

How useful are the coronary arteriographic images as a “truth standard” for establishing binodenoson-based MPI performance characteristics?



(Vote)

- 4. Do the phase 3 study results establish high binodenoson and adenosine MPI agreement?**
 - a. If you voted “yes,” discuss the aspects of the results that most impacted your opinion.**
 - b. If you voted “no,” discuss the types of data essential to establish high MPI agreement, including any important study design considerations.**